REMARKS

Applicants have received and carefully reviewed the Office Action mailed November 1, 2005, setting a three month shortened statutory period for reply ending February 1, 2005. Claims 49-53 and 55-69 remain pending. Reconsideration and reexamination are respectfully requested.

As a preliminary matter, the Examiner has stated various rejections, some of which rely on "Stein (4,498,478)" However, U.S. Patent No. 4,498,478 has an Ivan M. Bourgeois as named inventor, not Stein After review of the stated rejections and the Bourgeois reference, it appears that the Examiner intended to cite Bourgeois. Specifically, Figure 3 of the Bourgeois reference shows what appears to be a biphasic waveform having some degree of tilt, though no scale is given. The Examiner also correctly cites U.S Patent No. 4,498,478 to Bourgeois in the Notice of References Cited attached to the Office Action. Therefore, Applicants refer herein to Bourgeois.

In paragraph 2 of the Office Action, claims 49-53, 55-60 and 63-69 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Pub. No. 2002/0147475 to Scheiner et al After careful review of the cited reference, and in light of the above amendments, Applicants respectfully disagree.

It appears that each disclosed embodiment of Scheiner et al. illustrates the use of intracardiac electrodes for the delivery of pacing pulses. Each of independent claims 49, 53 and 55 have been amended to replace the previous recitation of subcutaneous position in the preamble. Instead, these aspects are now positively recited method steps in the claims. As such, the steps of subcutaneously positioning the ICD between the third rib and the twelfth rib of a patient and using a lead system that does not directly contact the patient's heart or reside in the intrathoracic blood vessels to provide the anti-bradycardia pacing energy to the heart are now positively recited. Because Scheiner et al. do not disclose such steps, the §102(e) rejection is overcome with respect to each of independent claims 49, 53 and 55, as well as dependent claims 50-52, 56-60, and 63-69.

In paragraph 4 of the Office Action, claims 61-62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sheiner et al. in view of U.S. Patent No. 4,498,478 to Bourgeois. Bourgeois is cited for showing a tilt on a pacing pulse. As noted above, independent claim 49 has been amended to positively recite the positioning of the ICD as well as the lead system.

Neither Sheiner et al. nor Bourgeois indicate a positioning as recited. Therefore, claims 61-62, which depend from claim 49, are believed to be patentable over the cited combination

In paragraph 5 of the Office Action, claims 49 and 53 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0082658 to Heinrich et al. In the previous Amendment, Applicants noted that the range of applied voltages to which the Heinrich et al. reference has an effective date prior to the filing of the present application would be limited to only a 100-volt pulse. The Examiner states, in paragraph 5 of the Office Action, that "It would have been obvious to one with ordinary skill in the art at the time the invention was made to optimize the monophasic waveform peak voltage as taught by Heinrich with monophasic waveforms having a peak voltage that is between approximately 25 V to approximately 50 V, and between approximately 50 V to approximately 75 V..." However, Applicants respectfully disagree.

First, Applicants note that the Examiner has not made a *prima facie* case of obviousness for subcutaneous pacing. The Examiner cites caselaw to the effect that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. However, the Examiner has not identified a reference providing a relevant range for pacing from a subcutaneous position. The Heinrich et al. provisional application identifies 100 volts, but no associated range. Neither low nor high ends to any associated range have been cited, aside from a single voltage. No other reference providing a relevant range has been cited. As such, the *prima facie* case has not been established.

Second, Applicants believe that Heinrich et al. teach away from the lower ranges suggested by the Examiner. The provisional application of Heinrich et al., which defines the relevant disclosure, does not support a modification to reduce the applied voltage. Applicants note the following discussion in the provisional application of Heinrich et al.:

> Figure 1 illustrates the detection method used during bradyarrhythmia monitoring. If asystole greater than, or equal to, a first predetermined time such as three seconds is detected at A, charging of output capacitors to a predetermined voltage such as 100 volts occurs during time B. At C, a first pacing pulse is delivered, and recharging of the capacitors begins at time D. Monitoring for an escape rate longer than a predetermined rate occurs until time E, at which time a

> second pacing pulse is delivered if an intrinsic beat does not occur. At time F, recharging occurs, and monitoring for the escape rate again proceeds. If such therapy is not discontinued because of the re-occurrence of the patient's intrinsic normal heart beat, the patient will be required to seek immediate emergency attention, since such therapy will be uncomfortable for the patient.

(U.S. Provisional App. No. 60/252,811, at page 5, lines 3-12.) Heinrich et al. state in this paragraph that a 100-volt pulse is applied for pacing, and will be uncomfortable to the patient. The application of such a pulse means "the patient will be required to seek immediate emergency attention, since such therapy will be uncomfortable for the patient." Heinrich et al. later identify "one hundred percent patient compliance" as an advantage of the system. Applicants believe that Heinrich et al. imply that application of a lesser pulse may not be advantageous, as this may reduce the compulsion of the patient to seek immediate medical attention.

This understanding is supported by Heinrich et al. repeatedly stating that the device is not intended for long-term use. For example.

> The transthoracic pacing provided by the current invention will likely be uncomfortable for the patient. Thus, this function is not intended to provide chronic therapy. Once therapy delivery has occurred for a bradyarrhythmic episode, a more traditional device should be implanted to provide long-term therapy.

(U S. Provisional App. No. 60/252,811, at page 4, lines 24-27.) Again.

> The above-described inventive system and method provides a therapy that avoids the risks of transvenous lead delivery. Such a system may be used for patients that are at-risk for arrhythmias, but have not yet experienced a confirmed arrhythmic episode. The device may therefore provide a needed long-term monitoring function, as well as any interventional therapy that is required. Preferably, after an episode is detected and therapy is delivered for a first time, the current system would be replaced with a more conventional implantable defibrillator.

(U.S. Provisional App. No. 60/252,811, at page 5, lines 16-22.) Later:

> In this example the patient has met two ACC/AHA Class I pacing indications; 1) Documented period of asystole greater than 3 seconds and 2) escape rate less than 40 bpm. This device has accomplished its intended function of monitoring for acute arrhythmias and delivering acute therapies and the patient would now be implanted with a traditional ICD (like a GEM II DR or VR). This device is intended to provide the "Lifeboat" function and is not intended to provide chronic therapies. Once the device begins delivering transthoracic pacing therapies (which will be painful) the patient should contact their physician or go to the nearest Emergency Room from the next step in the continuum of care.

(U.S. Provisional App. No. 60/252,811, at page A-2, §9.) Further:

> The problem which this invention is intended to solve: This implantable device and lead system is intended to provide physicians with a simple approach to protect patients at risk for life-threatening arrhythmias. This is a "Life-boat" device, capable of a limited number of defibrillation shocks and bradyarrhythmia pacing. The device is intended for long-term monitoring and the delivery of acute therapies. Once a patient has experienced an episode of life-threatening arrhythmias and the device has intervened with therapies, the device would be replaced with a more conventional implantable defibrillator, such as the Medtronic Model 7229, GEM II VR.

(U.S. Provisional App. No. 60/252,811, at page A-5, second paragraph.) Heinrich et al. repeatedly describe their device as providing long-term monitoring and acute therapy. The use of the suggested pacing voltage is at least partly motivated by a desire to cause the patient to seek immediate medical attention if pacing continues. The device is then replaced with a transvenous pacing device that does not create discomfort when a pacing pulse is applied.

In summary, the above illustrates that the Heinrich et al. provisional application contemplated a temporary treatment device intended to provide stimulus at energy levels that would be uncomfortable to the patient, prompting the patient to seek medical attention. Heinrich therefore teaches only the 100-volt stimulus in the provisional application. Reducing this voltage is not suggested by Heinrich as it would take away this function.

In light of the above, it is believed that a *prima facie* case of obviousness has not been established because no range for subcutaneous pacing has been identified by the Examiner.

Further, Applicants believe it would not be obvious to change the applied pacing voltage as the Examiner suggests. For each of these reasons, claims 49 and 53 are believed to be patentable over the cited reference.

In paragraph 6 of the Office Action, claims 50-52, 55-60, and 63-69 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Heinrich et al. publication as evidenced by the Heinrich et al. provisional application.

As before, the Examiner states that it would have been obvious to modify the ranges illustrated by Heinrich et al. in either the publication or the provisional application. In this instance, the Examiner finds that the provisional application suggests a pulse width of 50 milliseconds. Therefore, the Examiner states, it would have been obvious to select shorter pulse widths of lesser durations because patient specific factors determine what pulse is needed to effectively pace the heart. However, as above, Applicants believe that, at best, Heinrich et al. teaches on duration of pulse for pacing from a subcutaneous position. The Examiner has not identified any other reference teaching any other pulse width to constitute the "range" that one would select a pulse width from, meaning that a *prima facie* case of obviousness has not been shown. Moreover, Applicants believe that Heinrich et al. teach the application of a specific pulse that is designed to cause the patient to seek immediate medical assistance if pacing continues for any period of time. The discomfort suggested by Heinrich et al. teaches away from optimizing as suggested by the Examiner

It is believed that a *prima facie* case of obviousness has not been established. Further, the modification of the pulse duration taught by Heinrich et al. is unobvious in view of the Heinrich et al. provisional application. In light thereof, claims 50-52, 55-60, and 63-69 are believed to be patentable over the cited reference.

In paragraph 7 of the Office Action, claims 61-62 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Heinrich et al. published application in view of Bourgeois. It is believed that the above remarks and amendments with respect to independent claim 49, from which claims 61-62 depend, are sufficient to illustrate the patentability of each claim of Heinrich et al. Bourgeois does not provide any suggestion of pulse durations or amplitudes for subcutaneous pacing. Even if Bourgeois did provide such disclosure, it is believed that Heinrich

et al. would teach away from any necessary modification. Therefore, it is believed that claims 61-62 are patentable over the cited combination.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

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